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SHORT COMMUNICATION article

Effects of intra-tympanic platelet-rich plasma and conventional method in patients with tinnitus: A comparative study

Adeel M. Asghar

Department of Biotechnology, Islamia University of Bahawalpur, Bahawalpur, Punjab, Pakistan

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Abstract: Sensorineural hearing loss (SNHL) is a common form of hearing damage characterized by damage to the inner ear or auditory nerve, resulting in communication difficulties. Treatment of SNHL is difficult for many reasons. This study aimed to compare the effectiveness of intra-tympanic platelet-rich plasma versus conventional management through intra-tympanic steroid in patients with tinnitus. The study was designed as a quasi-experimental study and carried out at Pak-Emirates Military Hospital, Rawalpindi, Pakistan, from January-2025 to January 2026. A total of 50 patients with subjective complaints of tinnitus were included. They were divided into Group A (intra-tympanic platelet-rich plasma) and Group B (intra-tympanic steroid). The effectiveness of each intervention was assessed and compared between groups. Data were analyzed using the Mann-Whitney U-test. Median age was 34.5 years (49.0 - 24.0). There were 32 (64.0%) male and 18 (36.0%) female patients. Median duration of tinnitus was 6.5 weeks (10.0 - 5.0). Median pre-treatment THI score was 46.0 (56.0 - 29.0). Median post-treatment THI score at four weeks follow-up visit from the initiation of therapy in Group-A was 8.0 (22.0 - 3.0), while in Group-B it was 9.0 (18.0 - 2.0), statistically insignificant ($p = 0.546$). Effectiveness in Group-A ($n = 25$) was 21 (84.0%), while in Group-B ($n = 25$), it was 14 (56.0%), significant ($p = 0.031$). Thus, intra-tympanic platelet-rich plasma is significantly more effective for managing tinnitus as compared to the conventional management.

Introduction

Tinnitus is defined as a perception of the feeling of ringing in the ears without the presence of any physical auditory stimulus, which can be either temporary or permanent [1]. In itself, it is not a disease but can occur either as a component or a complication of middle ear disease [2, 3]. Some of the examples of etiologies that can lead to tinnitus include otosclerosis, chronic suppurative otitis media, Meniere's disease, tumors, certain neuromuscular diseases, and some medications [3, 4]. Tinnitus not only causes physical symptoms that cause persistent irritability but also leads to adverse psychological impacts that can lead to the development of depression and result in poor quality of life [5]. Mechanisms of tinnitus are complicated and still unknown. One widely accepted explanation for the occurrence of tinnitus is that it results from maladaptive neuroplastic changes following damage to the cochlear hair cells, which makes them unable to convey auditory information to the brain, causing neural gain that produces phantom sounds [6]. Given the complexity of the etiopathophysiological

mechanisms involved in the development of tinnitus, management of this condition becomes highly complex, and no single medication or intervention can be considered as one that fits all [7]. In this regard, two of the potential therapeutic interventions that have been widely used in the management of sensorineural hearing loss (of which tinnitus is a major complaint) are intra-tympanic platelet-rich plasma (PRP) and steroid injection [8]. However, their exact role in the management of tinnitus has not yet been established. In fact, there is limited literature regarding the effectiveness of these interventions in tinnitus, and, to the best of our knowledge, no regional studies have been conducted to date comparing these important therapeutic interventions for tinnitus. To address the important research question of how effective these interventions are in managing tinnitus and which amongst these is a better therapeutic choice, the present study was conducted with the aim of comparing the effectiveness of intra-tympanic platelet-rich plasma versus conventional management through intra-tympanic steroid in patients with tinnitus.

Materials and methods

This two-phase quasi-experimental study was conducted at Pak-Emirates Military Hospital (PEMH), Rawalpindi, Pakistan, from January 2024 to January-2025.

Sample size calculation was performed using the WHO sample size calculation. The sample size was calculated using a level of significance (α) of 5.0%, power (1-β) of 80.0%, population standard deviation (σ) of 3.78, population variance (σ2) of 14.28, and anticipated population mean values in intra-tympanic PRP (μ1) and steroid (μ2) groups of 16 and 13, respectively [9]. This gave a sample size (n) of 50 (25 in each group). The study sample was selected by using a non-probability consecutive sampling technique.

Inclusion criteria: Male and female patients, aged 18 to 50 years who presented with a subjective complaint of tinnitus for more than four weeks were included.

Exclusion criteria: Patients with ongoing middle ear infection, comorbid conditions (diabetes, malignancy, or autoimmune disease requiring steroid or immunosuppressant treatment), a known case of depressive illness, prior ear surgery, pre-existing perforation of the eardrum, and history of head injury were excluded.

Before inclusion in the study, informed written consent was obtained from the parent of every patient. After that, baseline characteristics including age, gender, duration of tinnitus, and pretreatment Tinnitus Handicap Inventory (THI) score were documented. Group allocation was performed based on the phase of the study. During the first phase extending from January to June 2024, patients were managed through intra-tympanic PRP and were allocated to Group-A. During the second phase from July to January 2025, patients were managed through intra-tympanic steroid injection and were allocated to Group-B.

For administrative intra-tympanic therapy, a uniform methodology was adopted in both groups. The first step was to anesthetize the ear by inserting a small cotton pledget impregnated with a local anesthetic agent (lidocaine 2.0%) into the ear and keeping it in place for 20 min. In the meantime, injections of PRP (0.5 mL of PRP made from the patient's own blood) and 2.0 mg of dexamethasone (made by drawing up 0.5 mL of injection dexamethasone 4.0 mg/mL) were prepared in separate 1.0 mL sterile syringes. The patient was then placed in the supine position with the head tilted 45 degrees toward the opposite side of the surgeon's standing position. Under direct visualization, the injection (as per group allocation) was then given intra-tympanically in the postero-inferior quadrant. After injection, patients were directed to remain in the same position for an additional 30 minutes. This process was repeated weekly for three consecutive weeks. Patients in both groups were given the same post-operative therapy for a period of three days, which comprised tablet Flurbiprofen 100 mg twice daily and capsule Cephradine 500 mg twice daily, after each injection. After one week of the last injection, i.e., four

weeks follow-up, patients were re-examined to get the post-treatment THI score. Based on this, effectiveness was defined as achievement of a THI score ≤ 10 at four weeks follow-up. In patients in whom there was failure to achieve effectiveness, alternative treatment was provided to the patient as per the advice of a senior otorhinolaryngologist with a minimum clinical expertise of more than three years.

Ethical considerations: This study was conducted in strict accordance with the ethical principles outlined in the Declaration of Helsinki (Institutional Ethics Committee, No: ERC/93/2025). All respondents were provided with a written cover letter detailing the study's objectives, guaranteeing absolute confidentiality.

Statistical analysis: Data were analyzed using Statistical Package for Social Sciences (SPSS) version 22. Quantitative variables (age, duration of tinnitus, and THI score) were presented as median interquartile range (IQR) after checking normality of data by the Shapiro-Wilk test, which showed that these were not distributed normally. Qualitative variables (gender and effectiveness) were presented as frequency and percentages. Post-treatment THI score was compared between groups using the Mann-Whitney U-test. Effectiveness was compared between groups using a Chi-square test. A p-value of ≤ 0.05 was considered significant.

Results

Fifty patients were included in this study. Median age was 34.5 (49.0 - 24.0) years. There were 32 (64.0%) male and 18 (36.0%) female patients. Median duration of tinnitus was 6.5 (10.0 - 5.0) weeks. Median pre-treatment THI score was 46.0 (56.0 - 29.0). Baseline characteristics of groups are compared in **Table 1**.

Table 1: Comparison of baseline characteristics between groups

Group	A (n = 25)	B (n = 25)	p-value
Median age years	34.0 (47.0 - 28.0)	36.0 (49.0 - 24.0)	0.846
Gender Male Female	15 (60.0%) 10 (40.0%)	17 (68.0%) 08 (32.0%)	0.556
Median duration of tinnitus in weeks	7.00 (10.0 - 5.0)	6.00 (10.0 - 5.0)	0.766
Median pretreatment THI score	47.0 (56.0 - 29.0)	45.0 (56.0 - 29.0)	0.540

THI = Tinnitus Handicap Inventory

Median post-treatment THI score at four weeks follow-up visit from the initiation of therapy in Group-A was 8.0 (22.0 - 3.0), while in Group-B it was 9.0 (18.0 - 2.0), (p = 0.546). This comparison of post-treatment THI score between groups is given in **Table 2**.

Table 2: Comparison of post-treatment THI score between groups

Group	A (n = 25)	B (n = 25)	P Value
Post-treatment THI score	8.00 (22.00 - 3.00)	9.00 (18.00 - 2.00)	0.546

THI = Tinnitus Handicap Inventory

Upon analysis of the effectiveness, which was defined as achievement of THI score ≤ 10 at four weeks follow-up, in Group-A (n = 25) it was 21 (84.0%) while in Group-B (n = 25), it was 14 (56.0%), (p = 0.031). Comparison of the effectiveness of intra-tympanic platelet-rich plasma versus conventional management through intra-tympanic steroid in patients with tinnitus is given in **Table 3**.

Table 3: Comparison of the effectiveness between groups

Group	A (n = 25)	B (n = 25)	p Value
Effectiveness	21 (84.0%)	14 (56.0%)	0.031

Discussion

The effectiveness of these two potent anti-inflammatory agents in the management of tinnitus was found that intra-tympanic PRP was a significantly more potent anti-inflammatory agent in comparison to intra-tympanic steroid injection for the management of tinnitus. Inflammation is one of the potential phenomena that has been hypothesized to be involved in the pathophysiology of tinnitus [10, 11]. Steroids have been well known as a highly potent therapeutic drug that can mitigate the inflammatory process [12-15]. This ability can potentially make it highly useful for managing tinnitus. Recently, therapeutic use of platelet-rich plasma has emerged globally in different clinical settings [16]. It also possesses anti-inflammatory properties since it contains the cytokines that can counteract the inflammatory process [17, 18].

The average age of the patients who presented with this common ear problem was 35 years, with 64.0% of the patients being males. One of the potential reasons for this male predominance is the higher chances of men being exposed to loud noises since they are more socially active owing to their role as the earner of a livelihood. Compared to this, Hackenberg et al. [19] reported that among all the patients with tinnitus, 59.73% were male, thus showing male predominance similar to the current study. Similarly, a study by Alanazi and others [20], which focused on the clinical characteristics and treatment patterns of tinnitus, reported a male predominance in this regard. Contrary to the gender trend of the present study, Al-Lahham and others [21] found female predominance regarding the distribution of tinnitus, with approximately 62.0% of the sufferers of this condition being females. Upon comparison of the effectiveness of intra-tympanic administration of PRP versus the corticosteroid injection among sufferers of tinnitus, it was found that although the THI scores were not significantly different among groups, the frequency of patients in which the effectiveness of the intervention was observed was significantly higher among patients treated with PRP given within the tympanic membrane compared to those treated conventionally by using intra-tympanic steroid injection. Similar to this non-significant difference between these two interventions based on post-treatment THI scores, Gupta and others [9] did not observe any statistical difference between these interventions in cases of tinnitus. Sharma and others [22] found that the frequency of effectiveness of intra-tympanic PRP in terms of subjective improvement in tinnitus was 47.1%, but this study primarily focused on improvement of sensorineural deafness rather than quantifying the improvement in tinnitus severity score. Ayub and others [23] focused on the role of intra-tympanic steroid injections in patients with this ear problem. It was found that the THI score was significantly improved after the administration of this intervention, making it a highly useful therapeutic option. Similarly, Yenez et al. [24] observed that administration of dexamethasone within the tympanic membrane significantly reduced the THI scores compared to the baseline levels and was found to be highly effective in this regard. Findings of the present study show a clear advantage of intra-tympanic administration of PRP for effectively managing patients suffering from non-resolving tinnitus.

Limitations: Etiological specification of tinnitus was not performed, and any patient with a subjective complaint of tinnitus was included without specifying the cause of it. Patients with potentially compromised wound healing due to diabetes or other conditions were not included, which could have impacted the results of the current study.

***Conclusion**:* Intra-tympanic platelet-rich plasma is significantly more effective for managing tinnitus as compared to the conventional management through intra-tympanic steroid.

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